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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,176	03/23/2006	Wolfgang Stachle	MERCK3155	6633
23599 7590 09/09/2010 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER				
OTTON, ALICIA L.				
ART UNIT		PAPER NUMBER		
1626				
NOTIFICATION DATE		DELIVERY MODE		
09/09/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

### Office Action Summary

**Application No.**

10/573,176

**Applicant(s)**

STAEHLE ET AL.

**Examiner**

Alicia L. Otton

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,5-11 and 14-38 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 14-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,9-11 and 30-38 is/are rejected.
- 7) ☒ Claim(s) 7 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

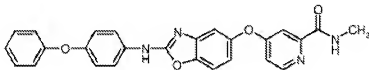
- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date \_\_\_\_\_
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1, 3, 5-11 and 14-38 are currently pending in the instant application. Claims 6 and 14-29 remain withdrawn for being drawn to a non-elected species/invention.

### *Response to Amendments and Arguments*

2. Applicant's arguments and amendments filed July 12, 2010 have been fully considered and entered into the application. All rejections and objections not explicitly maintained herein are withdrawn.
3. Applicant's claim amendments do not appear to overcome the previous rejections under 35 U.S.C. 102(e) and 103(a) because the compound



has been specifically added as a

limitation in claim 1. This is the same compound taught by Renhowe et al. applied in the previous Office action. Although the previous rejections are still maintained, because this amendment appears to be in error and the definition of R1 has been narrowed in the new claim set, the Examiner will extend the scope of the prior art search. In accordance with MPEP 803.02, the amended claims will be reexamined and the prior art search extended to the extent necessary to determine patentability of the Markush-type claim. The search was extended to a compound of Formula (I) wherein R<sub>2</sub> is R where R is H; R<sub>1</sub> is H; R<sub>3</sub> is H; X is SO<sub>2</sub>NH; Y is pyrimidinyl or isoxazole; and n=m=p=1. It is noted that the search was extended to include both

of these two species in order to expedite prosecution of this case. Because these species were not found allowable, the search was not extended further and the Markush claim was rejected.

***Maintained Objections***

4. Claims 1, 3, 5, 7-11 and 30-38 are objected to for containing non-elected subject matter. This objection can be overcome by submitting an amendment deleting the non-elected subject matter.
5. Claim 8 is objected to for being dependent upon a rejected base claim, but would not necessarily be allowable if rewritten in independent form.

***Maintained Claim Rejections- 35 U.S.C. § 102***

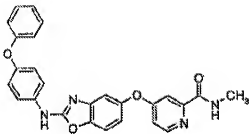
6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 3, 5, 9, 10 and 30-37 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Renhowe et al, WO 03/082272, which has a priority filing date back to March 29, 2002.

8. Renhowe et al. teaches the following compound which is identical to the instantly examined species, wherein the substituents are identified in paragraph 8 above. The compound is taught as compound 477 on page 96 of the reference. The compound has the following structure:



The reference also teaches that the compounds can be formulated into pharmaceutical compositions, either alone or in combination with one or more additional anti-cancer agents (see p. 8-9, with specific preferred examples recited on page 9). Therefore, the instant claims drawn to a pharmaceutical composition, and a pharmaceutical composition comprising the claimed compound and one or more additional active ingredients are also anticipated.

#### *New Claim Rejections- 35 U.S.C. § 102*

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

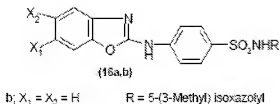
A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

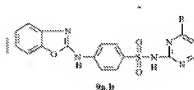
10. Claims 1, 3, 9, 10 and 30-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by El-Gaby et al, *J. Chin. Chem. Soc.* (2002), 49, pp. 407-414.

El-Gaby et al. teaches the following compound which reads on the instant claims. The compound is taught as compound 16b on page 409 of the reference. The compound has the following structure:



11. Claims 1, 3, 5, 9, 10 and 30-38 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by El-Gaby et al, *J. Chin. Chem. Soc.* (2004), 51, No. 2, pp. 327-333.

El-Gaby et al. teaches the following compound which reads on the instant claims. The compound is taught as compounds 9a and 9b on page 329 of the reference. The compound has the following structure:



where R is either H (9a) or Me (9b).

### ***Maintained Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Renhowe et al, WO 03/082272, in view of U.S. Patent No. 6,579,857, published June 17, 2003.

15. Please refer to paragraph 8 above for the relevant teachings of the '272 publication.

16. The '272 reference does not teach a kit of the instantly claimed compound and another active ingredient. However, it is well known in the pharmaceutical art that items can be separated and provided in a kit for the sake of convenience of packaging. The '857 patent states that the unit dose of a particular pharmaceutical agent "is formulated such that the first and second compositions are packaged together as a kit, but are not in admixture. A kit that includes each therapeutic agent packaged together in dosage form adds convenience for medical practitioners. Separate packaging of the two compositions permits administration by separate routes, at separate times, and/or at separate rates. Separate packaging also permits formulating each composition uniquely" (see column 9, paragraph 4).

17. Thus it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide the instantly claimed compound and additional active ingredients taught by the '272 publication in the form of a kit in order to conveniently package

the formulations so as to allow for either separate or simultaneous administration with unique formulation of compositions, if desired.

***Conclusion***

18. No claims are allowed
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia L. Otton whose telephone number is (571)270-7683. The examiner can normally be reached on Monday - Thursday 8:00-6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

/Golam M. M. Shameem/

Primary Examiner, Art Unit 1626

/Alicia L. Otton/  
Examiner, Art Unit 1626